USSN 09/975/350
Art Unit: 1618

This listing of claims will replace all prior versions and listings of claims in the application.

Listing of the Claims

1. (currently amended) A non-aqueous ~~particle-forming composition~~solution comprising a modafinil compound and at least one surfactant, characterized in that the ~~composition~~solution spontaneously forms an aqueous, liquid, homogeneous, stable composition of non-crystalline particles when contacted with an aqueous medium.

2. canceled.

3. (currently amended) The ~~composition~~solution of claim 1, wherein the modafinil compound is modafinil.

4. (currently amended) The ~~composition~~solution of claim 1, wherein the ~~composition~~solution is pharmaceutically acceptable.

5. canceled.

6. canceled.

7. canceled.

8. (currently amended) The ~~composition~~solution of claim 1, wherein the surfactant or surfactants comprise from about 0.5% to about 50% (w/w) of the ~~non-aqueous particle-forming composition~~solution.

9. (currently amended) The ~~composition~~solution of claim 8, wherein the surfactant or surfactants comprise from about 1% to about 20% (w/w) of the ~~non-aqueous particle forming composition~~solution.

10. (currently amended) The ~~composition~~solution of claim 1, wherein the surfactant or surfactants is a polyoxyethylene sorbitan fatty acid ester, a polyethylene glycol ether, a

saturated polyglycolized glyceride, a fatty acid ester of polyethylene glycol, a medium chain monoglyceride, a medium chain fatty acid ester, d-α-tocopheryl polyethylene glycol succinate, a polyethylene/propylene glycol copolymer, block copolymers of ethylene oxide and propylene oxide, a polyoxyl stearate, an ethoxylated castor oil, or an ethoxylated hydroxystearic acid.

11. (currently amended) The ~~composition~~solution of claim 10, comprising a first surfactant and a second surfactant.

12. (currently amended) The ~~composition~~solution of claim 11, wherein the second surfactant is a polyoxyethylene sorbitan fatty acid ester.

13. (currently amended) The ~~composition~~solution of claim 12, wherein the second surfactant is sorbitan monolaurate or Polysorbate 80.

14. (currently amended) The ~~composition~~solution of claim 1, further comprising an organic solvent.

15. (currently amended) The ~~composition~~solution of claim 14, wherein the organic solvent is at least one solvent selected from the group consisting of glycerin, propylene glycol, diethylene glycol ethyl ether, propylene carbonate, tetraglycol, a medium chain length monoglyceride, and a polyethylene glycol.

16. (currently amended) The ~~composition~~solution of claim 15, further comprising benzyl alcohol, α-phenethyl alcohol or β-phenethyl alcohol.

17. (currently amended) The ~~composition~~solution of claim 3, wherein modafinil is present in the ~~non-aqueous particle forming composition~~solution at a concentration of about 1 to about 500 mg/ml.

18. (currently amended) The ~~composition~~solution of claim 17, wherein modafinil is

present in the ~~non-aqueous particle-forming composition~~solution at a concentration of about 1 to about 200 mg/ml.

19. (currently amended) The ~~composition~~solution of claim 1, wherein the ~~non-aqueous particle-forming composition~~solution comprises a modafinil compound at a concentration of about 1 to about 100 mg/ml; a first surfactant selected from a polyoxyethylene sorbitan fatty acid ester, a polyethylene glycol ether, a saturated polyglycolized glyceride, a fatty acid ester of a polyethylene glycol, a medium chain monoglyceride, a medium chain fatty acid ester, d-α-tocopheryl polyethylene glycol succinate, a polyethylene/propylene glycol copolymer, block copolymers of ethylene oxide and propylene oxide, a polyoxyl stearate, an ethoxylated castor oil, and an ethoxylated hydroxystearic acid; a second surfactant selected from a polyoxyethylene sorbitan fatty acid ester; and an organic solvent selected from glycerin, propylene glycol, diethylene glycol ethyl ether, propylene carbonate, tetraglycol, a medium chain length monoglyceride, and a polyethylene glycol.

20. (currently amended) The ~~composition~~solution of claim 19, wherein the modafinil compound is modafinil.

21. (currently amended) The ~~composition~~solution of claim 20, wherein the first surfactant is a saturated polyglycolized glyceride, a fatty acid ester of a polyethylene glycol, or a medium chain monoglyceride; the second surfactant is a polyoxyethylene sorbitan fatty acid ester; and the organic solvent is a polyethylene glycol.

22. (currently amended) The ~~composition~~solution of claim 21, wherein the first surfactant is glyceryl caprylate/caprate, glyceryl monocaprylate or polyethoxylated (40) stearic acid; the second surfactant is sorbitan monolaurate; and the organic solvent is PEG-300 or PEG-400.

23. (currently amended) The ~~composition~~solution of claim 22, wherein the ~~non-aqueous particle-forming composition~~solution comprises 90% PEG-400, 5% sorbitan

monolaurate, 5% glyceryl caprylate/caprate (w/w/w).

24. (currently amended) The ~~composition~~solution of claim 22, wherein the ~~non-aqueous particle forming composition~~solution comprises 90% PEG-400, 5% sorbitan monolaurate, 5% glyceryl monocaprylate (w/w/w).

25. (currently amended) The ~~composition~~solution of claim 22, wherein the ~~non-aqueous particle forming composition~~solution comprises 90% PEG-400, 5% sorbitan monolaurate, 5% polyethoxylated (40) stearic acid (w/w/w).

26. (currently amended) The ~~composition~~solution of claim 21, wherein the first surfactant is glyceryl caprylate/caprate, glyceryl monocaprylate, polyethoxylated (40) stearic acid or a mixture of polyoxyethylene glyceryl caprylate and polyoxyethylene glyceryl caproate; the second surfactant is polyoxyethylene (80) sorbitan monooleate; and the organic solvent is PEG-300 or PEG-400.

27. (currently amended) The ~~composition~~solution of claim 26, wherein the ~~non-aqueous particle forming composition~~solution comprises 70% PEG-400, 15% polyoxyethylene (80) sorbitan monooleate, 15% glyceryl caprylate/caprate (w/w/w).

28. (currently amended) The ~~composition~~solution of claim 26, wherein the ~~non-aqueous particle forming composition~~solution comprises 70% PEG-400, 15% polyoxyethylene (80) sorbitan monooleate, 15% glyceryl monocaprylate (w/w/w).

29. (currently amended) The ~~composition~~solution of claim 26, wherein the ~~non-aqueous particle forming composition~~solution comprises 70% PEG-400, 15% polyoxyethylene (80) sorbitan monooleate, 15% polyethoxylated (40) stearic acid (w/w/w).

30. (currently amended) The ~~composition~~solution of claim 26, wherein the ~~non-aqueous particle forming composition~~solution comprises 70% PEG-400, 15% polyoxyethylene

(80) sorbitan monooleate, 15% of a mixture of polyoxyethylene glyceryl caprylate and polyoxyethylene glyceryl caproate (w/w/w).

31. (currently amended) The ~~composition~~solution of claim 10, wherein the ~~composition~~solution comprises Polysorbate 80, glyceryl caprylate/caprate and a mixture of glyceryl tricaprate and glyceryl tricaprilate.

32. (currently amended) The ~~composition~~solution of claim 1, comprising one or more unit doses of a modafinil compound.

33. (currently amended) The ~~composition~~solution of claim 32, comprising one unit dose of a modafinil compound.

34. (currently amended) The ~~composition~~solution of claim 33, wherein the unit dose comprises 200 mg of a modafinil compound.

35. (currently amended) The ~~composition~~solution of claim 33, wherein the unit dose comprises 100 mg of a modafinil compound.

36. (currently amended) A method of preparing an aqueous, liquid, homogeneous, stable composition of non-crystalline particles, comprising the steps of:

(a) preparing a non-aqueous ~~particle forming composition~~solution comprising a modafinil compound and at least one surfactant; and

(b) contacting the ~~non-aqueous particle forming composition~~solution with an aqueous medium to spontaneously form an aqueous, liquid, homogeneous, stable composition of non-crystalline particles.

37. (currently amended) The method of claim 36, wherein the ~~non-aqueous particle forming composition~~solution is contacted with an aqueous medium in vitro.

38. (currently amended) The method of claim 36, wherein the ~~non-aqueous particle-forming composition~~solution is contacted with an aqueous medium in vivo.

39. (original) The method of claim 36, wherein the modafinil compound is modafinil.

40. (previously presented) The method of claim 36, wherein the surfactant or surfactants are present in an amount from about 1% to about 50%.

41. (currently amended) A method of treating a disease or disorder in a subject, comprising administering to a subject a therapeutically effective amount of a non-aqueous ~~particle-forming composition of claim 1~~solution comprising a modafinil compound and at least one surfactant, wherein the solution is characterized by the fact that it spontaneously forms an aqueous, liquid, homogeneous, stable composition of non-crystalline particles when contacted with an aqueous medium~~to a subject~~.

42. (currently amended) A method of treating a disease or disorder in a subject, comprising:

(a) preparing a solution comprising a modafinil compound and at least one surfactant;

~~(a)~~(b) contacting the ~~non-aqueous particle-forming composition~~solution ~~of claim 1~~ with an aqueous medium to form an aqueous, liquid, homogeneous, stable composition of non-crystalline particles; and

~~(b)~~(c) administering a therapeutically effective amount of the aqueous, liquid, homogeneous, stable composition of non-crystalline particles to a subject.

43. (previously presented) The method of claim 40, wherein the modafinil compound is modafinil.

44. (currently amended) The method of claim 41, wherein the ~~composition~~solution is administered for the treatment of sleepiness, tiredness, Parkinson's disease, cerebral ischemia, stroke, sleep apneas, eating disorders, attention deficit hyperactivity disorder, cognitive

dysfunction or fatigue; or for the promotion of wakefulness, stimulation of appetite, or stimulation of weight gain to a patient in need thereof.

45. (currently amended) The ~~composition~~solution of claim 3, wherein upon administration of the ~~composition~~solution to a subject in need thereof, modafinil has a blood serum level of about 0.05 to about 30 μg/ml in said subject.

46. (currently amended) The ~~composition~~solution of claim 45, wherein the blood serum level is from about 1 to about 20 μg/ml.

47. (currently amended) The ~~composition~~solution of claim 1, wherein the ~~non-aqueous particle forming composition~~solution is suitable for oral administration to a subject.

48. (currently amended) The ~~composition~~solution of claim 47, wherein the ~~non-aqueous particle forming composition~~solution is encapsulated within a capsule.

49. (currently amended) The ~~composition~~solution of claim 48, wherein the capsule is a soft gelatin capsule.

50. (currently amended) The ~~composition~~solution of claim 48, wherein the capsule is a hard capsule.

51. canceled.

52. canceled.

53. canceled.

54. canceled.

55. (currently amended) The ~~composition~~solution of claim 1, wherein the modafinil compound is the levorotatory form of modafinil.

56. (previously presented) The method of claim 36, wherein the modafinil compound is the levorotatory form of modafinil.

57. (currently amended) The ~~composition~~method of claim 40, wherein the modafinil compound is the levorotatory form of modafinil.

58. (currently amended) The ~~composition~~method of claim 41, wherein the modafinil compound is modafinil.

59. (currently amended) The ~~composition~~solution of claim 14, wherein the organic solvent has an average molecular weight of about 1500 daltons or less.

60. (previously presented) The method of claim 42, wherein the modafinil compound is modafinil.

61. (currently amended) The method of claim 42, wherein the ~~composition~~solution is administered for the treatment of sleepiness, tiredness, Parkinson's disease, cerebral ischemia, stroke, sleep apneas, eating disorders, attention deficit hyperactivity disorder, cognitive dysfunction or fatigue; or for the promotion of wakefulness, stimulation of appetite, or stimulation of weight gain to a patient in need thereof.

62. canceled.

63. (currently amended) The ~~composition~~solution of claim 19, wherein the modafinil compound is the levorotatory form of modafinil.

64. (currently amended) The ~~composition~~method of claim 41, wherein the modafinil compound is the levorotatory form of modafinil.

65. (currently amended) The ~~composition~~method of claim 42, wherein the modafinil

compound is the levorotatory form of modafinil.

66. (new) The solution of claim 18, wherein modafinil is present in the solution at a concentration of about 20 to about 80 mg/ml.

67. (new) The solution of claim 1, wherein the solution is a liquid solution.

68. (new) The solution of claim 1, wherein the solution is a solid solution.